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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,443	05/18/2005	Bertrand Saunier	NIH341.001NP	4458

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,443	SAUNIER ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *4,8 and 14-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,7 and 9-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/18/2006 and 7/3/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received December 18, 2006.

Election/Restrictions

Applicant's election with traverse of group I, claims 1-3, 5-7, and 9-13 is acknowledged. Applicant argues that the restriction requirement is improper because according to MPEP 803, there are two criteria for a proper restriction requirement: (A) The inventions must be independent or distinct, and (B) There would be serious burden on the examiner if restriction is not required. Examiner points out that the present application was filed under 35 U.S.C. 371. When application is filed under 35 U.S.C. 371, (1) the different groups of claims should be listed and (2) an explanation should be given for why each group lacks unity with each other group. The lack of unity of invention was discussed in the restriction requirement of October 23, 2006, (1) the different groups of claims were listed and (2) an explanation was given for why each group lacks unity with each other group (i.e., why there is no single general inventive concept) and the unique special technical feature was described. See MPEP 1893.03(d). The inventions of groups I, II, III, IV, V, and VI do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding technical feature. Thus the restriction is deemed proper and is made FINAL.

Claims 4, 8, 14-22 are withdrawn because they are drawn to the non-elected invention. Claims 1-3, 5-7, and 9-13 are under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on April 18, 2006 and July 3, 2006 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the Examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-7, and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumert et al. (Journal of Virology, May 1998, IDS of 7/3/2006) as evidenced by USBiological Technical Data Sheet and SIGMA Product Information Sheet.

Claims are drawn to a method for isolating infection defective hepatitis C virus like particles from cells infected with a baculovirus encoding HCV structural proteins, one VLP comprises: E 1 and E2-p7, and another VLP comprises E1 and E2 without p7 proteins. The method comprises incubating the cells in hypertonic solution and hypotonic solution, lysing the infected cells, adding polyethylene glycol, fractionating the precipitate by gradient ultracentrifugation, incubating the cells in a buffer containing digitonin and protease inhibitors, and centrifuging the lysate through a cushion comprising a monosaccharide, disaccharide or polysaccharide. The isolated particles are 50 nm in diameter.

The specification discloses [0054] that the hypertonic buffer is for example Hepes plus glycerol, and the hypotonic buffer is for example Hepes. The specification also discloses that it is also possible to use other components or steps to achieve successive treatment in a hypertonic buffer and a hypotonic buffer. For example, sucrose or hypertonic saline solution can be followed by hypotonic shock.

Baumert et al. disclose a method for isolating infection defective hepatitis C virus like particles from cells infected with a baculovirus encoding HCV structural proteins (see the entire document). Baumert et al. disclose isolation of two VLP constructs: E1 and E2-p7, and another VLP construct comprising E1 and E2 without p7 proteins, particles are 50 nm in diameter (see Figure 1, Figure 4 and Materials and Methods –Baculovirus constructs and insects cell cultures, and page 3831). The method disclosed by Baumert et al. comprises incubating the cells in hypertonic solution and hypotonic solution, lysing the infected cells, adding polyethylene glycol, fractionating the precipitate by gradient ultracentrifugation, incubating the cells in a buffer containing digitonin and protease inhibitors, and centrifuging the lysate through a cushion comprising sucrose, which is a disaccharide (see Materials and Methods -Purification of HCV-like particles, and page 3831). It is noted that Baumert et al. does not use the name polyethylene glycol, but NP-40. NP-40 is a brand name for polyethylene glycol (see USBiological Technical Data Sheet, under Synonyms). It is also noted that Baumert et al. does not use the name protease inhibitors but specifically names the inhibitors. Aprotinin and Leupeptin used in Baumert's method are protease inhibitors as evidenced by SIGMA Product Information Sheet. The ultracentrifugation in Baumert's method is performed under exact the same parameters as

described in Example 6 of the specification, Beckman SW55 rotor; 40,000rpm, 2h, 4°C). Thus Baumert et al. anticipates the current claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AB

Agnieszka Boesen, Ph.D.

3/16/2007

Stacy B. Chen 3/16/07